

SEP 11 2000

K002722

510(k) Summary

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**MODELS HD-503 AND HD-505
NONINVASIVE BLOOD PRESSURE MEASUREMENT SYSTEM**

1. **COMPANY INFORMATION.** *Name:* Jawon Medical Co., Ltd.
Address: 7F Jeong Ju Bldg., 1451-38 Seocho-Dong, Seocho-Ku, Seoul, Korea
Phone: (011) 82-2-587-4056 *Contact:* Mr. Won-Hee Park, President
2. **DEVICE IDENTIFICATION.** *Trade name:* Models HD-503 and HD-505, Digital Blood Pressure Monitors
Common Name and Classification Name: Noninvasive Blood Pressure Measurement System, 74 DXN
3. **PREDICATE DEVICES.** The legally marketed devices to which substantial equivalence will be demonstrated are the following devices:
 - 1) Model HD-502 Manual Digital Blood Pressure Monitor, manufactured by Jawon Medical Co., Ltd., and cleared for marketing under 510(k) No. K000675, SE decision Mar./14/2000;
 - 2) Models HD-1000S and HD-2000F Fuzzy Type Digital Blood Pressure Monitors, manufactured by Jawon Medical Co., Ltd., and cleared for marketing under 510(k) No. K983855, SE decision Nov./17/1998
4. **DEVICE DESCRIPTION.** *General:* Jawon Models HD-503 and HD-505 are compact digital blood pressure monitor intended for measurement of blood pressure at the brachial artery. The systems use the oscillometric method of operation. The plug-in type pneumatic cuff with built-in semiconductor strain gauge is automatically inflated by built-in pump. The systems are microprocessor controlled and includes pushbutton operating controls, circuitry to detect and process minute pressure oscillation; a six-digit LCD display of systolic and diastolic pressure readings and heart rate; and a memory function that stores the previous eight measurement results.
Operation: Pressurization is automatically governed. If the initial inflation pressure is inadequate for measurement, i.e. lower than the patient's systolic pressure, the pump will automatically repressurize to a level about 20 mmHg (in Model HD-503) or 30 mmHg (in Model HD-505) above the initial level. Symbols in the LCD indicate pressurization status at all times. The device employs a pressure measurement algorithm designed to detect, filter,

process, and store pressure readings. In the event of excessive cuff pressure, the systems display an error signal, and open the high-speed exhaust valve immediately.

Power: The Models HD-503 and HD-505 systems are powered by four 1.5-volt size AA batteries. Power is shut down automatically if the unit remains idle for a period of approximately two minutes.

5. **INTENDED USES.** The Models HD-503 and HD-505 systems are the noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients, age 18 and above. Because the devices are recommended for in a home care environment, use should be limited to patients capable of understanding written and/or oral directions.
6. **COMPARISON WITH PREDICATE DEVICES.** The Models HD-503 and HD-505 systems have been compared with the Jawon Models HD-1000S and HD-2000F Digital Blood Pressure Monitors, and with Jawon Model HD-502 Manual Digital Blood Pressure Monitor. The intended use of the three systems is the same. The principle operation (oscillometric measurement) and many operating features are identical. The only substantive difference between the subject and predicate devices is that one of predicate device, Model HD-502, incorporates a squeeze bulb for cuff inflation and other devices incorporate an air pump, instead of the manual means of cuff inflation. All systems maintain a constant bleed down rate during deflation and measurement through the use of an electronic air release valve. All systems present measurement results digitally on a six-digit LCD and are powered by four 1.5 batteries. All systems offer the measurement range with 20 to 320 mmHg. It is concluded that there are no technologic differences between the subject and predicate devices that raise new questions concerning either safety or effectiveness.
7. **PERFORMANCE DATA.** The measurement performance of the Jawon systems have been evaluated in accordance with ANSI/AAMI Standard SPI0-1992 and found to comply with the accuracy criteria established in the standard. Safety testing including electrical characteristics of the systems and components, life testing over 10,040 operational cycles, intra-device variability, environmental integrity under various operating and storage conditions including high and low altitude extremes, and resistance to vibration and shock has been conducted with satisfactory results. Similarly, electromagnetic compatibility compliance studies have been conducted by ONETECH Testing & Evaluation Laboratories, and the device was found to comply with all applicable safety and performance standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

FEB 1 6 2001

Jawon Medical Co., Ltd
c/o Mr. Robert Moonstra
Engineering Group Leader
Compliance Assessment Service
Underwriters Laboratories
2600 NW Lake Road
Camas, WA. 98607-8542

Re: K002722
Trade Name: Digital Blood Pressure Monitor HD-503 and HD-505
Regulatory Class: II (two)
Product Code: DXN
Dated: August 29, 2000
Received: August 31, 2000

Dear Mr. Boonstra:

This letter corrects our substantially equivalent letter of September 11, 2000 regarding the incorrect identification of the product code "DPW" for your digital blood pressure monitors. The correct code has been corrected and is identified above as DXN (21 CFR 870.1130).

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.


A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further

announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


for

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (If Known): K002722

Device Name: Digital Blood Pressure Monitor, Models HD-503 and HD-505

Indications for use:

Noninvasive measurement of systolic and diastolic blood pressure and heart rate in adult patients, i.e., age 18 and above, in a home care environment.

(Please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over-the-Counter Use

X

[Signature]
(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K002722